

§ 95.1121

§ 95.1121 Specific requirements for wireless medical telemetry devices operating in the 1395–1400 and 1427–1432 MHz bands.

Due to the critical nature of communications transmitted under this part, the frequency coordinator in consultation with the National Telecommunications and Information Administration shall determine whether there are any Federal Government systems whose operations could affect, or could be affected by, proposed wireless medical telemetry operations in the 1395–1400 MHz and 1427–1432 MHz bands. The locations of government systems in these bands are specified in footnotes US351 and US352 of § 2.106 of this chapter.

[75 FR 19285, Apr. 14, 2010]

§ 95.1123 Protection of medical equipment.

The manufacturers, installers and users of WMTS equipment are cautioned that the operation of this equipment could result in harmful interference to other nearby medical devices.

§ 95.1125 RF safety.

Portable devices as defined in § 2.1093(b) of this chapter operating in the WMTS are subject to radio frequency radiation exposure requirements as specified in §§ 1.1307(b) and 2.1093 of this chapter. Applications for equipment authorization of WMTS devices must contain a statement confirming compliance with these requirements. Technical information showing the basis for this statement must be submitted to the Commission upon request.

§ 95.1127 Station identification.

A WMTS station is not required to transmit a station identification announcement.

§ 95.1129 Station inspection.

All WMTS transmitters must be available for inspection upon request by an authorized FCC representative.

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Subpart I—Medical Device Radiocommunication Service (MedRadio)

SOURCE: 74 FR 22709, May 14, 2009, unless otherwise noted.

§ 95.1201 Eligibility.

Operation in the MedRadio service is permitted by rule and without an individual license issued by the FCC. Duly authorized health care professionals are permitted to operate MedRadio transmitters. Persons may also operate MedRadio transmitters to the extent the transmitters are incorporated into implanted or body-worn medical devices that are used by the person at the direction of a duly authorized health care professional; this includes medical devices that have been implanted in that person or placed on the body of that person by or under the direction of a duly authorized health care professional. Manufacturers of medical devices that include MedRadio transmitters, and their representatives, are authorized to operate transmitters in this service for the purpose of demonstrating such equipment to duly authorized health care professionals. No entity that is a foreign government or which is acting in its capacity as a representative of a foreign government is eligible to operate a MedRadio transmitter. The term “duly authorized health care professional” means a physician or other individual authorized under state or federal law to provide health care services. Operations that comply with the requirements of this part may be conducted under manual or automatic control.

§ 95.1203 Authorized locations.

MedRadio operation is authorized anywhere CB station operation is authorized under § 95.405, except that use of Medical Body Area Network devices in the 2360–2390 MHz band is restricted to indoor operation within a health care facility registered with the MBAN coordinator under § 95.1225. For the purposes of this subpart, health care facilities are limited to hospitals and other establishments, both Federal and non-Federal, that offer services, facilities

and beds for use beyond a 24 hour period in rendering medical treatment.

[79 FR 60099, Oct. 6, 2014]

§ 95.1205 Station identification.

A station is not required to transmit a station identification announcement.

§ 95.1207 Station inspection.

Any non-implanted MedRadio transmitter must be made available for inspection upon request by an authorized FCC representative. Persons operating implanted or body-worn MedRadio transmitters shall cooperate reasonably with duly authorized FCC representatives in the resolution of interference.

§ 95.1209 Permissible communications.

(a) Except for the purposes of testing and for demonstrations to health care professionals, MedRadio programmer/control transmitters may transmit only non-voice data containing operational, diagnostic and therapeutic information associated with a medical implant device or medical body-worn device that has been implanted or placed on the person by or under the direction of a duly authorized health care professional.

(b) Except as provided in § 95.627(b) no MedRadio implant or body-worn transmitter shall transmit except in response to a transmission from a MedRadio programmer/control transmitter or in response to a non-radio frequency actuation signal generated by a device external to the body with respect to which the MedRadio implant or body-worn transmitter is used.

(c) MedRadio programmer/control transmitters may be interconnected with other telecommunications systems including the public switched telephone network.

(d) For the purpose of facilitating MedRadio system operation during a MedRadio communications session, as defined in § 95.627, MedRadio transmitters in the 401–406 MHz band may transmit in accordance with the provisions of § 95.627(a) for no more than 5 seconds without the communications of data; MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(2) and (b)(3) for no more than

3.6 seconds in total within a one hour time period; and MedRadio transmitters may transmit in accordance with the provisions of § 95.627(b)(4) for no more than 360 milliseconds in total within a one hour time period.

(e) MedRadio programmer/control transmitters may not be used to relay information in the 401–406 MHz band to a receiver that is not included with a medical implant or medical body-worn device. Wireless retransmission of information intended to be transmitted by a MedRadio programmer/control transmitter or information received from a medical implant or medical body-worn transmitter shall be performed using other radio services that operate in spectrum outside of the 401–406 MHz band.

(f) MedRadio programmer/control transmitters and medical implant transmitters may not be used to relay information in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands to a receiver that is not part of the same Medical Micropower Network. Wireless retransmission of information to a receiver that is not part of the same Medical Micropower Network must be performed using other radio services that operate in spectrum outside of the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands. Notwithstanding the above restrictions, a MedRadio programmer/control transmitter of an MMN may communicate with the MedRadio programmer/control transmitter of another MMN to coordinate transmissions so as to avoid interference between the two MMNs.

(g) Medical body-worn transmitters may relay only information in the 2360–2400 MHz band to a MedRadio programmer/control transmitter or another medical body-worn transmitter device that is part of the same Medical Body Area Network (MBAN). A MedRadio programmer/control transmitter may not be used to relay information in the 2360–2400 MHz band to other MedRadio programmer/controller transmitters. Wireless retransmission of all other information from an MBAN transmitter to a receiver that is not part of the same MBAN shall be performed using other radio services that operate in spectrum outside of the 2360–2400 MHz band. Notwithstanding

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the above restriction, a MedRadio programmer/control transmitter in the 2360–2400 MHz band may communicate with another MedRadio programmer/control transmitter in the 2360–2400 MHz band to coordinate transmissions so as to avoid interference between the two Medical Body Area Networks.

(h) MedRadio programmer/control transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands shall not transmit with a duty cycle greater than 3 percent.

[74 FR 22709, May 14, 2009, as amended at 75 FR 52477, Aug. 26, 2010; 77 FR 4269, Jan. 27, 2012; 77 FR 55733, Sept. 11, 2012; 79 FR 60100, Oct. 6, 2014]

§ 95.1211 Channel use policy.

(a) The channels authorized for MedRadio operation by this part of the FCC Rules are available on a shared basis only and will not be assigned for the exclusive use of any entity.

(b) To reduce interference and make the most effective use of the authorized facilities, MedRadio transmitters must share the spectrum in accordance with §§ 95.627 or 95.628.

(c) MedRadio operation is subject to the condition that no harmful interference is caused to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, or to other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, 451–457, and 2360–2400 MHz bands. MedRadio stations must accept any interference from stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, or Earth Exploration Satellite Services, and from other authorized stations operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, 451–457, and 2360–2400 MHz bands.

[74 FR 22709, May 14, 2009, as amended at 77 FR 4270, Jan. 27, 2012; 77 FR 55733, Sept. 11, 2012]

§ 95.1213 Antennas.

(a) An antenna for a MedRadio transmitter shall not be configured for permanent outdoor use.

(b) Any MedRadio antenna used outdoors shall not be affixed to any structure for which the height to the tip of

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the antenna will exceed three (3) meters (9.8 feet) above ground.

(c) Paragraphs (a) and (b) of this section do not apply to MedRadio operations in the 2390–2400 MHz band.

[79 FR 60100, Oct. 6, 2014]

§ 95.1215 Disclosure policies.

(a) Manufacturers of MedRadio transmitters operating in the 401–406 MHz band must include with each transmitting device the following statement:

“This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (*i.e.*, transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

(b) Manufacturers of MedRadio transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands must include with each transmitting device the following statement:

“This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

(c) Manufacturers of MedRadio transmitters operating in the 2360–2400 MHz

band must include with each transmitting device the following statement:

“This transmitter is authorized by rule under the MedRadio Service (47 CFR part 95). This transmitter must not cause harmful interference to stations authorized to operate on a primary basis in the 2360–2400 MHz band, and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the MedRadio Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.”

[77 FR 4270, Jan. 27, 2012, as amended at 77 FR 55733, Sept. 11, 2012]

§ 95.1217 Labeling requirements.

(a)(1) MedRadio programmer/control transmitters operating in the 401–406 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

“This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.”

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

(2) MedRadio programmer/control transmitters operating in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

“This device may not interfere with stations authorized to operate on a primary basis in the 413–419 MHz, 426–432 MHz, 438–444 MHz, and 451–457 MHz bands, and must accept any interference received, including interference that may cause undesired operation.”

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

(3) MedRadio programmer/control transmitters operating in the 2360–2400 MHz band shall be labeled as provided in part 2 of this chapter and shall bear the following statement in a conspicuous location on the device:

“This device may not interfere with stations authorized to operate on a primary basis in the 2360–2400 MHz band, and must accept any interference received, including interference that may cause undesired operation.”

The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.

(b) Where a MedRadio programmer/control transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to the main control unit.

(c) MedRadio transmitters shall be identified with a serial number, except that in the 2360–2400 MHz band only the MedRadio programmer/controller transmitter shall be identified with a serial number. The FCC ID number associated with a medical implant transmitter and the information required by § 2.925 of this chapter may be placed in the instruction manual for the transmitter and on the shipping container for the transmitter, in lieu of being placed directly on the transmitter.

[74 FR 22709, May 14, 2009, as amended at 77 FR 4270, Jan. 27, 2012; 77 FR 55734, Sept. 11, 2012]

§ 95.1219 Marketing limitations.

Transmitters intended for operation in the MedRadio Service may be marketed and sold only for the permissible communications described in § 95.1209.

§ 95.1221 RF exposure.

A MedRadio medical implant device or medical body-worn transmitter is subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307(b) and 2.1093 of this chapter, as

appropriate. Applications for equipment authorization of devices operating under this section must demonstrate compliance with these requirements using either finite difference time domain (FDTD) computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that supporting documentation and/or specific absorption rate (SAR) measurement data be submitted.

[78 FR 33653, June 4, 2013]

§ 95.1223 Registration and frequency coordination.

(a) *Registration.* Prior to operating MBAN devices that are capable of operation in the 2360–2390 MHz band, a health care facility, as defined by § 95.1203, must register with a frequency coordinator designated under § 95.1225. Operation of MBAN devices in the 2360–2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination (to the extent coordination is required under paragraph (c) of this section) is complete. The registration must include the following information:

(1) Specific frequencies or frequency range(s) within the 2360–2390 MHz band to be used, and the capabilities of the MBAN equipment to use the 2390–2400 MHz band;

(2) Effective isotropic radiated power;

(3) Number of MedRadio programmer/control transmitters in use at the health care facility as of the date of registration including manufacturer name(s) and model numbers and FCC identification number;

(4) Legal name of the health care facility;

(5) Location of MedRadio programmer/control transmitters (*e.g.*, geographic coordinates, street address, building);

(6) Point of contact for the health care facility (*e.g.*, name, title, office, phone number, fax number, email address); and

(7) In the event an MBAN has to cease operating in all or a portion of the 2360–2390 MHz band due to interference under § 95.1211 or changes in coordination under paragraph (c) of this

section, a point of contact (including contractors) for the health care facility that is responsible for ensuring that this change is effected whenever it is required (*e.g.*, name, title, office, phone number, fax number, email address). The health care facility also must state whether, in such cases, its MBAN operation is capable of defaulting to the 2390–2400 MHz band and that it is responsible for ceasing MBAN operations in the 2360–2390 MHz band or defaulting traffic to other hospital systems.

(b) *Notification.* A health care facility shall notify the frequency coordinator whenever an MBAN programmer/control transmitter in the 2360–2390 MHz band is permanently taken out of service, unless it is replaced with transmitter(s) using the same technical characteristics and locations as those reported on the health care facility's registration which will cover the replacement transmitter(s). A health care facility shall keep the information contained in each registration current and shall notify the frequency coordinator of any material change to the MBAN's location or operating parameters. In the event that the health care facility proposes to change the MBAN's location or operating parameters, the MBAN coordinator must first evaluate the proposed changes and comply with paragraph (c) of this section, as appropriate, before the health care facility may operate the MBAN in the 2360–2390 MHz band under changed operating parameters

(c) *Coordination procedures.* The frequency coordinator will determine if an MBAN is within the line of sight of an AMT receive facility in the 2360–2390 MHz band and notify the health care facility when it may begin MBAN operations under the applicable procedures in (c)(1) or (2) of this section.

(1) If the MBAN is beyond the line of sight of an AMT receive facility, it may operate without prior coordination with the AMT coordinator, provided that the MBAN coordinator provides the AMT coordinator with the MBAN registration information and the AMT coordinator concurs that the MBAN is beyond the line of sight prior to the MBAN beginning operations in the band.

(2) If the MBAN is within line of sight of an AMT receive facility, the MBAN frequency coordinator shall achieve a mutually satisfactory coordination agreement with the AMT frequency coordinator prior to the MBAN beginning operations in the band. Such coordination agreement shall provide protection to AMT receive stations consistent with International Telecommunication Union (ITU) Recommendation ITU-R M.1459, "Protection criteria for telemetry systems in the aeronautical mobile service and mitigation techniques to facilitate sharing with geostationary broadcasting-satellite and mobile-satellite services in the frequency bands 1 452-1 525 and 2 310-2 360 MHz," May 2000, as adjusted using generally accepted engineering practices and standards that are mutually agreeable to both coordinators to take into account the local conditions and operating characteristics of the applicable AMT and MBAN facilities, and shall specify when the device shall limit its transmissions to segments of the 2360-2390 MHz band or shall cease operation in the band. This ITU document is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and approved by the Director of Federal Register. Copies of the recommendation may be obtained from ITU, Place des Nations, 1211 Geneva 20, Switzerland, or online at <http://www.itu.int/en/publications/Pages/default.aspx>. You may inspect a copy at the Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. "Generally accepted engineering practices and standards" include, but are not limited to, engineering analyses and measurement data as well as limiting MBAN operations in the band by time or frequency.

(3) If an AMT operator plans to operate a receive site not previously analyzed by the MBAN coordinator to determine line of sight to an MBAN facility, the AMT operator shall consider

using locations that are beyond the line of sight of a registered health care facility. If the AMT operator determines that non-line of sight locations are not practical for its purposes, the AMT coordinator shall notify the MBAN coordinator upon no less than 7 days' notice that the registered health care facility must cease MBAN operations in the 2360-2390 MHz band unless the parties can achieve a mutually satisfactory coordination agreement under paragraph (c)(2) of this section.

[77 FR 55734, Sept. 11, 2012, as amended at 79 FR 60100, Oct. 6, 2014]

§ 95.1225 Frequency coordinator.

(a) The Commission will designate a frequency coordinator(s) to manage the operation of medical body area networks by eligible health care facilities.

(b) The frequency coordinator shall perform the following functions:

(1) Register health care facilities that operate MBAN transmitters, maintain a database of these MBAN transmitter locations and operational parameters, and provide the Commission with information contained in the database upon request;

(2) Determine if an MBAN is within line of sight of an AMT receive facility in the 2360-2390 MHz band and coordinate MBAN operations with the designated AMT coordinator as specified in § 87.305 of this chapter;

(3) Notify a registered health care facility when an MBAN has to change frequency within the 2360-2390 MHz band or to cease operating in the band consistent with a coordination agreement between the MBAN and the AMT coordinators;

(4) Develop procedures to ensure that registered health care facilities operate an MBAN consistent with the coordination requirements under § 95.1223; and

(5) Identify the MBAN that is the source of interference in response to a complaint from the AMT coordinator and notify the health care facility of alternative frequencies available for MBAN use or to cease operation consistent with the rules.

(c) The frequency coordinator shall:

(1) Provide registration and coordination of MBAN operations to all eligible health care facilities on a non-discriminatory basis;

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(2) Provide MBAN registration and coordination services on a not-for-profit basis;

(3) Notify the Commission of its intent to no longer serve as frequency coordinator six months prior to ceasing to perform these functions; and

(4) Transfer the MBAN registration data in usable form to a frequency coordinator designated by the Commission if it ceases to be the frequency coordinator.

[77 FR 55735, Sept. 11, 2012, as amended at 79 FR 60100, Oct. 6, 2014]

EFFECTIVE DATE NOTE: At 79 FR 60100, Oct. 6, 2014, § 95.1225 was amended by adding paragraph (c), however, this paragraph contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

Subpart J—Multi-Use Radio Service (MURS)

SOURCE: 65 FR 60878, Oct. 13, 2000, unless otherwise noted.

GENERAL PROVISIONS

§ 95.1301 Eligibility.

An entity is authorized by rule to operate a MURS transmitter if it is not a foreign government or a representative of a foreign government and if it uses the transmitter in accordance with § 95.1309 and otherwise operates in accordance with the rules contained in this subpart. No license will be issued.

§ 95.1303 Authorized locations.

(a) MURS operation is authorized:

(1) Anywhere CB station operation is permitted under § 95.405; and

(2) Aboard any vessel of the United States, with the permission of the captain, while the vessel is travelling either domestically or in international waters.

(b) MURS operation is not authorized aboard aircraft in flight.

(c) Anyone intending to operate a MURS unit on the islands of Puerto Rico, Desecheo, Mona, Vieques, and Culebra in a manner that could pose an interference threat to the Arecibo Observatory shall notify the Interference Office, Arecibo Observatory, HC3 Box 53995, Arecibo, Puerto Rico 00612, in

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writing or electronically, of the location of the unit. Operators may wish to consult interference guidelines, which will be provided by Cornell University. Operators who choose to transmit information electronically should e-mail to: *prcz@naic.edu*.

(1) The notification to the Interference Office, Arecibo Observatory shall be made 45 days prior to commencing operation of the unit. The notification shall state the geographical coordinates of the unit.

(2) After receipt of such notifications, the Commission will allow the Arecibo Observatory a period of 20 days for comments or objections. The operator will be required to make reasonable efforts in order to resolve or mitigate any potential interference problem with the Arecibo Observatory. If the Commission determines that an operator has satisfied its responsibility to make reasonable efforts to protect the Observatory from interference, the unit may be allowed to operate.

[65 FR 60878, Oct. 13, 2000, as amended at 70 FR 31374, June 1, 2005]

§ 95.1305 Station identification.

A MURS station is not required to transmit a station identification announcement.

§ 95.1307 Permissible communications.

(a) MURS stations may transmit voice or data signals as permitted in this subpart.

(b) A MURS station may transmit any emission type listed in § 95.631(j) of this chapter.

(c) MURS frequencies may be used for remote control and telemetering functions. MURS transmitters may not be operated in the continuous carrier transmit mode.

(d) MURS users shall take reasonable precautions to avoid causing harmful interference. This includes monitoring the transmitting frequency for communications in progress and such other measures as may be necessary to minimize the potential for causing interference.

[67 FR 63290, Oct. 11, 2002]